ISPE Boston Area Chapter Presents:
AUTOMATION:
At the Crossroads with IT Interfaces

Thursday, May 16, 2013
5:30 pm to 8:30 pm
Genzyme Center
500 Kendall Street, Cambridge, MA 02142

PROGRAM SUMMARY:
Should process control automation be interfaced with IT infrastructure? To answer that question, perhaps we can learn from the sage advice of Yogi Berra, who famously once said, “When you come to a fork in the road…take it.” When we consider where process control automation is headed and the demands of new paradigms like knowledge management and Stage 3-Continued Process Verification, such interfaces are quickly becoming a necessity rather than an option. Attendees will learn about the changing role of the automation engineer, as well as some of the drivers and issues.

PRESENTATION ONE:
Process Data Management and the Changing Role of the Automation Engineer
As the need for business and process data grows, companies are commissioning more specialized computerized systems, sometimes with a great deal of overlap leading to redundant data being stored in multiple systems. ANSI/ISA95 (Enterprise-Control System Integration) addresses this problem by setting standards for communications within the enterprise layers of manufacturing and operations. The role of the automation engineer is being transformed into that of a business analyst in order to streamline processes such as materials management, computerized maintenance, and procurement. Service Oriented Architecture, Web Services, and OPC communications will be discussed. Systems to be explored include DCS, MES, EDMS, EQMS, CMMS, and Plant Historians.

SPEAKER ONE:
Jordan Croteau is an Automation Engineer in Biogen Idec Cambridge Manufacturing Engineering. Jordan has served as technical lead for numerous projects on process automation and control and IT systems, with a process data management focus. Before Biogen Idec, Jordan spent three years working for automation integrators and process skid manufacturers. Jordan earned a Bachelor of Science in Chemical Engineering from Worcester Polytechnic Institute, and is a member of the International Society of Automation (ISA) and an Information member of the ISA95, ISA18, and ISA100 committees.

PRESENTATION TWO:
Implementing an Equipment Monitoring System with an Operations Information Infrastructure
This presentation describes the installation of an automated Equipment Monitoring System providing “review by exception” electronic reports with automated routing and e-signature approvals to replace an existing manual paper-based GMP record for logging equipment temperature readings, and related process data and information.

Continued on next page...
Thursday, May 16, 2013
5:30 pm to 8:30 pm

**Genzyme Center**
500 Kendall Street, Cambridge, MA 02142

**PRESENTATION TWO Continued:**
The execution of this project required the implementation of a site-wide Operations Information Infrastructure which will also be discussed as the basis on which future “electronic initiative” application projects will be integrated.

**SPEAKER TWO:**
**Kenneth S. Kovacs** is the QA Business Systems Manager at Fujirebio Diagnostics, Inc. in Malvern, PA and a Certified Management Consultant (CMC). He has in-depth knowledge in Life Sciences Industry operations, manufacturing, and technology transfer through 35 years of experience working with companies including Johnson & Johnson, TAVA Technologies, and Rockwell Automation.

Ken is an active member of ISPE and GAMP America’s MES SIG. He is an original member of the ISA-95 committee that developed the “Enterprise-Control System Integration” international standard, a past Director of ISA’s Food and Pharmaceutical Industries Division, and a co-author of both the textbook “Automation and Validation of Information in Pharmaceutical Processing” and the GAMP® Good Practice Guide: Manufacturing Execution Systems Control and Compliance”. Ken has a Bachelor of Engineering degree from Villanova University and an MBA from Xavier University.

**SPEAKER THREE:**
**Glenn Restivo** is the Director of Business Development Life Sciences, Chemicals, Food and Nutrition for M+W Automation. His role is to develop and promote automation and manufacturing IT solutions for pilot and commercial manufacturing addressing industry, business and regulatory challenges. He focuses his efforts on meeting the customer’s time to market, minimizing project risk, optimizing solutions and using state of the art technology that supports project lifecycle and asset management.

He received a bachelor’s degree in chemical engineering from Stevens Institute of Technology in Hoboken, New Jersey. In addition, he actively participates with the International Society for Pharmaceutical Engineers (ISPE), MIT’s Center for Biomedical Innovation (CBI), Rutgers Engineering Research Center (ERC), Next Generation Pharma Workshops and has articles on PAT/QbD and RFID published in key industry trade magazines.

**MEETING MANAGER:**
**Robert J. Wherry**, Principal Consultant, Strategic Compliance Services, PAREXEL International
ISPE Boston Area Chapter Presents:
AUTOMATION:
At the Crossroads with IT Interfaces

Thursday, May 16, 2013
5:30 pm to 8:30 pm
Genzyme Center
500 Kendall Street, Cambridge, MA 02142

PROGRAM SCHEDULE:
5:30 – 6:30 PM Registration & Networking Reception
6:30 – 8:30 PM Welcome & Program

REGISTRATION FEES:

<table>
<thead>
<tr>
<th>Category</th>
<th>Registration by 05/09/2013</th>
<th>After 05/09/2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members</td>
<td>$50</td>
<td>$60</td>
</tr>
<tr>
<td>Non-members</td>
<td>$95</td>
<td>$115</td>
</tr>
<tr>
<td>Students</td>
<td>FREE</td>
<td>FREE</td>
</tr>
</tbody>
</table>

** Attendees may only attend one program as a non-member.

REGISTRATION IS NOW OPEN ONLINE!

Don’t waste time filling in the form! Register online at www.ISPEBoston.org/Events.
Pay by credit card OR check.

Name: ____________________________________ Title: ____________________________________
Do you wish to opt out of being listed on the attendee roster:    ☐
Company: __________________________________ Member #: __________________________
Address: __________________________________ City: __________________ State: _______ Zip: _____________
Tel: __________________ Fax: __________________ Email: __________________

PAY BY CREDIT CARD:  ☐ Visa  ☐ MasterCard  ☐ American Express
Card #: ___________________ Expiration Date: ___________________
Cardholder Name (as it appears on card): __________________________
Cardholder Signature: _________________________________________

Payment may be mailed to: ISPE, Boston Area Chapter, 411 Waverley Oaks Road, Suite 331B, Waltham, MA 02452
Telephone: 781-647-ISPE (4773) ☏ Fax: 781-647-7222 ☏ Email: office@ispeboston.org

**PLEASE NOTE: CANCELLATIONS RECEIVED AFTER May 9th ARE SUBJECT TO BILLING**
ISPE Boston Area Chapter Presents:
AUTOMATION:
At the Crossroads with IT Interfaces

Thursday, May 16, 2013
5:30 pm to 8:30 pm

Genzyme Center
500 Kendall Street, Cambridge, MA 02142

DIRECTIONS AND PARKING:

From the Expressway North/South
Take the exit for Storrow Drive
Follow Storrow Drive to the Kendall Square/Government Center exit
Follow the signs for Kendall Square
Cross the Longfellow Bridge and into Cambridge
After crossing the river, take a right at the first set of lights onto Third Street
Turn right onto Kendall Street
The parking garage is on your right

From the Massachusetts Turnpike (I-90 Eastbound)
Take the Mass Turnpike East
Take Exit 18 (Allston/Cambridge)
Follow signs toward Cambridge/Somerville
The Doubletree Guest Suites Hotel will be on your right
At the traffic light take a right onto Storrow Drive
Do not cross the river
Take the Kendall Square/Government Center exit off Storrow Drive
Follow the signs for Kendall Square, bearing left around the rotary and across the Longfellow Bridge into Cambridge
After crossing the river, take a right at the first set of lights onto Third Street
Turn right onto Kendall Street
The parking garage is on your right

From the “T”
Take the Red Line to the Kendall Square stop
When you exit the station, you will be on Main Street
Walk East - towards Boston - and you will see a traffic light at the corner of Broadway and Third Street
Cross at the intersection and walk down Third Street
Take your first right onto Kendall Street
Genzyme Center is the first building on the left